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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CLOW, LORI A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 01/27/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,628

Applicant(s)

YIP ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11-21-02.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: _____

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DETAILED ACTION

Applicant's election without traverse of Group II in Paper No. 13 is acknowledged. Claims 3, and 4-15 are currently pending. It is noted that Applicant has indicated that claims 3 and 14-15 were pending, however, in the original restriction requirement, Group II consisted of claims 3 and 4-15-in-part. Applicant is requested to amend the claims to reflect the restriction election.

Information Disclosure Statement

The IDS, filed 1 June 2001, has been entered and considered. An initialed copy of the form PTO-1449 is included with this office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 3-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Kauvar et al. (WO 98/32017, 23 July 1998; PTO-1449).

Kauvar et al. describe methods to identify compounds that can the insulin receptor, potentiates the insulin activation of the insulin receptor, potentiates the stimulation by insulin of cellular glucose uptake, stimulates the uptake of glucose in cells displaying the insulin receptor, etc. (page 5, line 26-page 6, line 12), meeting the limitations of all of claims 3-15. The particulars of the invention are directed to utilization of the three-dimensional structure of the

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insulin receptor to model conformational changes (page 11, lines 4-13). Several screening assays may also be employed that detect conformational changes (see pages 11-15) and critical sites are identified such that assays may be designed to identify compounds that have a variety of metabolic effects, all related to modulating the insulin receptor. Kauvar et al. meet all of the limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauri et al. (Journal of Computer-Aided Molecular Design (1994) vol.8, pages 51-66) in view of Christiansen et al. (PNAS (1991) vol.88, pages 249-252).

Lauri et al. (1994) describe a computer program known as CAVEAT, which was designed to facilitate the structure-based design of enzyme inhibitors and related biologically active molecules (see introduction). In detail, the program is organized such that one program processes a database of 3D structures to determine orientation of all the relevant pair-wise combinations of bonds in the individual molecules. From this, an index of this source database is prepared and finally a search of the index can be performed for molecules that match a particular query. CAVEAT has various programs that allow the user to store and retrieve 3D structures, superimpose structures to query targets, etc. (page 52, 3rd paragraph). Once target vectors are assigned for query pairs, screening and clustering can be performed. In the CLASS part of the program, a complex structure and framework evaluation can be evaluated for use as templates in antagonist or agonist design (see discussion).

Lauri et al. do not specifically refer to the insulin receptor however Christiansen et al. (1991) do disclose the elucidation of the quaternary structure of the human placental insulin receptor using electron microscopy with negative-staining techniques (see entire paper for structure specifics).

While this particular quaternary structure of insulin may have not been previously elucidated, the instant invention is directed to nonfunctional descriptive material in that the

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structure which is fed into the computer algorithm is simply a set of data utilized for comparisons using a series of processing steps, and does not impose a change in the processing steps. The method to compare data does not become non-obvious merely because new data are available (see *In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983). When there is no functional relationship between matter which is, by itself, non-statutory subject matter and a substrate (e.g. a computer), there is no reason to give patentable weight to the content (of the non-statutory subject matter). The structure of insulin recited in the claims does not distinguish the claimed method from the prior art in terms of patentability, and the claims are obvious.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

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January 22, 2003

Lori A. Clow, Ph.D.

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Lori A. Clow



MARY K. ZEMAN
PRIMARY EXAMINER

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